REMARKS/ARGUMENTS

Claims 1-24 remain pending.

Support for each amended claim is found throughout the originally filed specification and the originally filed claims. Additionally, support for the feature of present Claim 11 "in a human eye" is found, for example, at originally filed Claim 11 that describes a "Therapeutic method for improving the level of L-ascorbic acid in a human eye."

Upon entry of the amendment, Claims 1-24 will be active.

No new matter is believed to have been added.

The written description and new matter rejections of Claims 11-23 are believed to be obviated by the amendment of Claim 11. Applicants respectfully note the language in the preamble of present Claim 11 is found *ispis verbs,* for example, at originally filed Claim 11; and that originally filed Claim 11 is part of the originally filed specification. Accordingly, written description support exists for the preamble of present Claim 11, and the preamble of present Claim 11 is not new matter. Withdrawal of the written description and new matter rejections is requested for present Claim 11 and the claims depending therefrom.

The obviousness rejection of Claims 1-10 and 24 as being unpatentable in view of Nelson combined with Fritsch is respectfully traversed.

The Official Action, at pages 2-3, describes, in maintaining the obviousness rejection, that "Applicant is reminded that the lower limit of Nelson et al. is very close to the higher limit of the claimed invention." "Furthermore, the determination of optimum pH is considered to be within the skill of the artisan in the absence of evidence to the contrary."

Applicants respectfully submit that even if these statements were true, and Applicants contest the truth of these statements, the Office has missed the point of Applicants arguments.

MPEP 2143.01 V describes, in part, that "the proposed modification cannot render the prior art unsatisfactory for its intended purpose" (underlining emphasis added).

Thus, according to MPEP 2143.01 V, any modification that renders the prior art unsatisfactory for its intended purpose is not a proper basis for an obviousness rejection.

Applicants respectfully note that there is no requirement that the modification be a large modification.

Thus, to again quote the Office, even if "the lower limit of Nelson et al. is very close to the higher limit of the claimed invention," the Office's assertion is irrelevant in responding to Applicant's MPEP 2143.01 V argument. The assertion is irrelevant because the modification, as proposed by the Office, even if it is a small modification, "renders the prior art unsatisfactory for its intended purpose."

Applicants note that present Claim 1 is drawn to "a composition comprising a salt of L-ascorbic acid with a pharmaceutically acceptable organic base, and a pharmaceutically acceptable inert vehicle, wherein the pH of the composition ranges from 5.0 to 5.6" (underlining emphasis added).

Nelson, at column 3, lines 46-48, describes "In addition the pH of the solution is critical. If the solution pH is outside of the range of pH 6-9, the lenses will be adversely affected" (underlining emphasis added). Because Nelson is drawn to a method for sterilizing contact lenses, and Nelson describes that modifying the pH of Nelson's method will "adversely effect" the contact lenses Nelson is sterilizing, the Office's proposed modification renders Nelson unsatisfactory for Nelson's intended purpose.

Further, Fritsch describes that it is "conventionally known, in the art, that a pH of 6.8 to 7.2 is necessary to keep [the]...ibuprophen in solution" (See Fritsch, column 1, line 66-column 2, line 2). Modifying Fritsch, as the Office has suggested, would make the ibuprophen precipitate out of Fritsch's solution, thereby rendering Fritsch's solution unsatisfactory for its intended purpose.

The obviousness rejection, as proposed by the Office, renders the cited references unsatisfactory for their intended purposes. The nature of the modification (the Office has argued it is small) is irrelevant because the Office's modifications render the cited references unsatisfactory for their intended purposes. Accordingly, the obviousness rejection is improper and MUST be withdrawn.

Further, Applicants respectfully traverse the obviousness rejection of present Claims 1-10 and 24, as being unpatentable over Nelson in view of Fritsch because the references do not describe or suggest all of the features of present Claims 1-10 and 24, and in fact "teach away from" a feature of these claims.

Present Claims 1-10 and 24 include the feature that "the pH of the composition ranges from 5.0 to 5.6." This feature is not described or suggested by Nelson and Fritsch, and in fact, is "taught away from" by both Nelson and Fritsch.

The Office, in failing to acknowledge this important distinction, finds itself un-enviably taking a position contrary to that of the Court of Appeals for the Federal Circuit and the MPEP.

MPEP 2141.03 VI describes, in part, that "a prior art reference must be considered in its entirety, i.e., as a whole, including positions that would lead away from the claimed invention." (Note: emphasis on the word whole is the MPEP's).

MPEP 2144.05 III describes, in part, that "a *prima facie* case of obviousness may also be rebutted by showing that the art, in any material aspect, teaches away from the claimed invention."

In In re Gurley, 27 F.3d 551 31 USPQ2d 1130 (Fed. Cir. 1994), the Federal Circuit held that "A reference may be said to teach away when a person of ordinary skill, upon

reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant."

In the present case, both Nelson and Fritsch teach away, in a material aspect, from the feature of present Claims 1-10 and 24, "that the pH of the composition ranges from 5.0 to 5.6." Accordingly, present Claims 1-10 and 24, are not obvious in view of Nelson and Fritsch.

Nelson, at column 3, lines 46-48, describes "In addition the pH of the solution is critical. If the solution pH is outside of the range of pH 6-9, the lenses will be adversely affected" (underlining emphasis added).

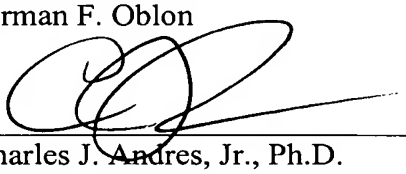
The examples of Fritsch, describe a pH of 6.8 and 6.8 (see Examples 1 and 2, at column 4, of Fritsch), as well as a pH of "about 6.7" in Claim 2. Further, Fritsch describes that it is "conventionally known, in the art, that a pH of 6.8 to 7.2 is necessary to keep [the]...ibuprophen in solution" (See Fritsch, column 1, line 66-column 2, line 2, underlining emphasis added).

Accordingly, one of ordinary skill in the art, to quote the Federal Circuit "would be led in a direction divergent from the path that was taken by the applicant," by Fritsch and Nelson, because Fritsch and Nelson both show a criticality of keeping the pH at a range of 6-9, more preferably from about 6.7 to 7.2. Fritsch and Nelson, in describing the criticality of keeping the pH in the above described ranges "so that the ibuprophen stays in solution" and so that "the lenses are not adversely effected," "teach away from," according to the Federal Circuits' definition, the pH feature of present Claims 1-10 and 24. As described above, this "teaching away" is exactly the kind of secondary consideration envisioned by the MPEP to rebut a *prima facie* case of obviousness.

Applicants submit the present application is now in condition for allowance. Early notification to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Charles J. Andres, Jr., Ph.D.
Attorney of Record
Registration No. 57,537

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 06/04)